

**510(k) Summary of Safety & Effectiveness**


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**Submitter** Vanguard Medical Concepts, Inc.  
5307 Great Oak Drive  
Lakeland, FL 33815

DEC 11 2002

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**Contact** Mike Sammon, Ph.D.  
Director, Research and Development  
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**Date** August 21, 2002

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**Device**

- Trade Names: Vanguard Reprocessed Ultrasonic Scalpels
- Common Name: Ultrasonic surgical instrument, Ultrasonic hand instruments
- Classification: 21 CFR 878.4400 – Electrosurgical cutting and coagulation device and accessories – Class II
- Product Code LFL

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**Indications for Use** The Reprocessed Ultrasonic Scalpel is intended for use during minimally invasive laparoscopic and open surgical procedures where coagulation and incision of soft tissue is required.

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**Contra-indications** This instrument is not intended for contraceptive tubal ligation or for bone excision.

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**Predicate Devices** Trocars legally marketed by the following original equipment manufacturers (OEM) and 3<sup>rd</sup> party reprocessor:

OEM - Reprocessor	Trade Name
Ethicon Endo-Surgery, Inc.	Ultracision® Harmonic Scalpel®
United States Surgical	AutoSonix™ ULTRASHEARS™
Sterilmed, Inc.	Reprocessed Harmonic Scalpels

*Continued on next page*

## 510(k) Summary of Safety & Effectiveness, Continued

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### **Device Description**

The Reprocessed Ultrasonic Scalpel is a previously used medical device that has been cleaned, tested, inspected, packaged, and sterilized by Vanguard Medical Concepts (VMC). Scalpels are available in 5mm and 10mm diameters with functional lengths of 14-38cm. The instrument jaws are opened and closed using proximal ring handles, available with a pistol or scissor grip style. The instrument tip and shaft can be rotated 360° in either direction using a knob on the handle. Scalpels are available with various blade configurations: curved shears, straight shears, blunt, knife-down.

The proximal handle is designed for attachment to a compatible handpiece and microprocessor controller. Electrical outputs from the controller are converted by an ultrasonic transducer within the handpiece to mechanical vibrations that are transmitted through the instrument shaft to the distal scalpel blade.

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### **Technological Characteristics**

The Vanguard reprocessed ultrasonic scalpels are essentially identical to the currently marketed OEM devices. No changes are made to the currently marketed device specifications and they possess the same technological characteristics. Materials and performance testing demonstrate that the reprocessed scalpels are equivalent to predicate devices and continue to be safe and effective for their intended use.

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### **Test Data**

Cleaning, sterilization, and packaging validations; and performance and materials testing all demonstrate that the reprocessed devices perform as intended and are safe and effective.

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### **Conclusion**

Based on the information provided herein and the 510(k) "Substantial Equivalence" Decision Making Process Chart, we conclude that the Vanguard reprocessed ultrasonic scalpels are substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

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DEC 11 2002

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Vanguard Medical Concepts, Inc.  
Mike Sammon, Ph.D.  
Director, Research and Development  
5307 Great Oak Drive  
Lakeland, Florida 33815

Re: K022780

Trade/Device Name: Vanguard Reprocessed Ultrasonic Scalpel  
Regulatory Class: Unclassified  
Product Code: LFL  
Dated: November 25, 2002  
Received: November 27, 2002

Dear Dr. Sammon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in

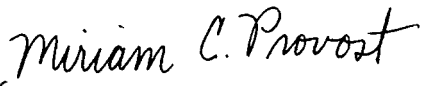
Page 2 – Dr. Mike Sammon

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

*for*   
Celia M. Witten, Ph.D., MD  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number: K 022780

Device Name: Vanguard Reprocessed Ultrasonic Scalpels

### Indications for Use:

Reprocessed ultrasonic scalpel is intended for use during minimally invasive laparoscopic and open surgical procedures where coagulation and incision of soft tissue is required.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒

OR

Over-the-Counter Use ☐

(Per 21 CFR 801.109)

Miriam C. Provost

(Optional Format 1-2-96)

(Division Sign-Off)

Division of General, Restorative  
and New Medical Devices

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510(k) Number: K 022780

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